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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/091,561	08/21/98	PLOUET J	USB95ARCNR

000466 HM12/0312
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EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	18

DATE MAILED: 03/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/091,561	Plouet et al.
Examiner	**Group Art Unit**
G. R. Ewoldt	1644

☒ Responsive to communication(s) filed on 9/11/00, 9/29/00, 12/29/00.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *18-35* is/are pending in the application.

Of the above, claim(s) *18-24 and 31* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25-30 and 32-35* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

1. Claims 25-30 and 32-35 are pending and being acted upon.

2. The disclosure is objected to because of the following informalities:
Figure 5 contains no legend and is thus indecipherable.

Applicant appears to misunderstand the phrase, "no legend". "No legend" does not mean that the figure has not been labeled as Figure 5 (which it has), it means that the lines defined by the open circle, open square, and closed circle have not been defined and thus cannot be deciphered. Note, for example, the legend in the top left corner of Figure 4.

3. In view of Applicant's amendments, remarks, and declaration, filed 9/11/00, 9/29/00, and 12/29/00, all previous rejections have been withdrawn. Applicant's remarks, filed 9/11/00, and declaration, filed 9/29/00, concerned the previous rejections under 35 U.S.C. 102(b), 103(a), and 112, second paragraph. Said remarks and declaration do not present support or arguments that would address the new rejections under 35 U.S.C. 112, first paragraph.

4. The following are New Grounds of Rejection necessitated by Applicant's amendments and declaration, filed 9/11/00, 9/29/00, and 12/29/00.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-30 and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation.

The declaration under 37 CFR 1.132 filed 9/29/00 is insufficient to overcome the rejection of claims 25-30 and 32-35 based upon 35 U.S.C. 112, first paragraph, for the following reasons:

Regarding making the anti-idiotypic (α-id) vascular endothelial growth factor (VEGF) antibodies, the claims would include both polyclonal and monoclonal antibodies. The specification discloses only the production of polyclonal antiserum containing polyclonal antibodies. The declaration of Jean Plouet however, teaches that the production of said polyclonal antiserum containing polyclonal antibodies would not result in the claimed invention. The declaration teaches that the additional key steps of producing and screening monoclonal antibodies is required to make the antibodies of the claims. The declaration further shows that of four monoclonal antibodies derived from cells taken from an animal producing a polyclonal response, said response having been induced by the methods of the instant claims resulting in a polyclonal antiserum from which the polyclonal antibodies of the instant claims would be isolated, just a single monoclonal antibody (A11) having the claimed property (of binding flk-1 and not flt) was produced. Thus, the inventor's own declaration teaches that a polyclonal antiserum, and antibodies purified therefrom, produced by the disclosed method, could not be made and would not function as claimed, i.e., bind flk-1 and not flt. Said polyclonal antibodies would comprise a significant number of antibodies that bound both flk-1 and flt, or flt alone. See particularly the figure on page 5 of the Plouet declaration, filed 9/29/00, which teaches that the disclosed method would also produce antibodies such as A2, A3, and A9 which do not meet the limitations of the claims. In summary, the declaration teaches that only a monoclonal antibody, for which there is no support in the specification, could function as claimed. Thus the specification does not teach how to make the claimed antibody because an antibody made by the method disclosed in the specification would not meet the limitations of the claims. Because the specification does not adequately describe how to make the claimed invention, said making would be highly unpredictable and requiring of undue experimentation.

Regarding how to use the α-id VEGF antibodies, Claims 27 and 28 are drawn to Fab fragments of said antibodies. However, inventor Plouet states in his declaration, filed 9/29/00, "Fab fragments ... in no case, can induce a function similar to that exerted by the anti-idiotypic antibody, namely, receptor dimerization, internalization and cell proliferation," (page 8). Thus, Fab fragments are not enabled for their intended use.

Therefore, because the specification does not adequately describe how to make or use the claimed invention, said making or use would be highly unpredictable and requiring of undue experimentation.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice, i.e., make and use, the claimed invention.

7. No claim is allowed.

8. Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

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Technology Center 1600
March 7, 2001

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